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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,105	08/15/2001	Fred S. Lamb	875.054US1	9991

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,105	LAMB ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-24,27-29,31-35 and 38-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24,27-29,31-35,38-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed June 7, 2006 have been received and entered into the application.

Action Summary

Upon reconsideration, the rejection of claims 22-24, 27-36 and 38-43 under 35 U.S.C. 112, first paragraph is withdrawn.

The rejection of claims 22-24,27-29, 33-35, 39-43 under 35 U.S.C. 102(b) as being anticipated by Delaney et al. (1996) evidenced by Kifor et al. (U.S. Patent No. 5,658,936) all of record is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 31, 32 and 38 under 35 U.S.C. 103(a) as being unpatentable over Delaney et al. (1996) as applied to claims 22-24,27-29, 33-35, 39-43 above, and further in view of Zhang et al. (U.S.Patent No. 6,266,560 B1) and Drug Facts and Comparisons, 1997 all of record is being maintained for the reasons stated in the previous Office Action.

Applicant's amendment necessitated an additional of rejection presented in this Office action as follows:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-24, 27-36 and 38-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terms "male patient" in claim 22 is not supported in the original specification as filed. The instant specification on page 21, lines 13-14, defines the term "patient" as any living organism with vascular smooth muscle, such as a mammal, and, in particular, a human. However, the terms "male patient" is not specifically disclosed in the definition of specification as originally filed. This is a New Matter rejection.

The remaining claims are rejected to the extent that they depend on claim 22.

Response to Arguments

Applicant's arguments filed June 7, 2006 have been fully considered but they are not persuasive. Applicant argues Delaney et al. fails to anticipate the present claims because Delaney et al. discloses that one male patient on a tamoxifen regimen had

experienced increased libido during his course of treatment and that in order for Delaney et al. to teach that the patient, condition to be treated and the effect be the same as the claimed invention, Delaney et al. would need to teach a method of administering tamoxifen to a male patient having compromised vascular tissue associated with erectile dysfunction in order to modulate the vascular tone in the patient having compromised vascular tissue associated with erectile dysfunction; a method to modulate penile vascular tone, and a method of treating erectile dysfunction, and that Delaney et al. does not teach these methods. This is not persuasive because that the patient being treated by Delaney et al. had **enhanced** libido upon administration of tamoxifen is the indication that the patient had compromised vascular tissue associated with erectile dysfunction since the libido was **enhanced**. In other words, the patient was already suffering from libido in order to have an **enhanced** effect. Further, when tamoxifen treatment was continued, the libido condition was returned to normal which is indicates that tamoxifen normalized the libido condition during this time period of treatment, which anticipates the claimed modulation of penile vascular tone upon administration of same compound with same amounts of same population suffering from enhanced libido. Applicant argues that it is important to note that the onset of increased libido did not occur until the patient had been taking tamoxifen for about four month and when the patient was reevaluated in January of 1995, his libido had returned to normal levels despite the fact that he continued tamoxifen treatment; the patient's increased libido was not observed until the patient had been on tamoxifen for a several months, and it resolved before the patient discontinues his tamoxifen treatment; the

period of time in which he had an increased libido was not co-extensive with the period of time in which he was administered tamoxifen. This is not persuasive because it is not about the tamoxifen caused enhanced libido, rather, it is about the tamoxifen normalized the enhanced libido condition of the patient during the time period wherein the patient had enhanced libido. In this case, Delaney et al. continued tamoxifen in the patient while the patient was suffering from enhanced libido, to decrease the enhanced libido condition in the patient back to normal. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-24,27-29, 33-35, 39-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Delaney et al. (1996) evidenced by Kifor et al. (U.S. Patent No. 5,658,936) all of record.

Delaney et al. teach that patient treated with tamoxifen significantly enhanced libido and reported that Patient's libido has returned to normal. (under Case Report, second paragraph, under Discussion).

Applicants' recitation in claims of mechanism of action to modulate vascular tone and reduces penile sympathetic tone does not represent a patentable limitation by which tamoxifen gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects (enhance erection) which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel since the treatment of the conditions encompassed by the claims.

Kifor et al. report that an improvement in erectile function is defined as increased libido. (column 6, line 66- column 7, lines 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31, 32 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delaney et al. (1996) as applied to claims 22-24,27-29, 33-35, 39-43 above, and further in view of Zhang et al. (U.S.Patent No. 6,266,560 B1) and Drug Facts and Comparisons, 1997 all of record.

Delaney et al. as applied as before.

Delaney et al. do not expressly teach route of administration set forth in claims 32 and 38 and further administering the agents set forth in claim 31.

Zhang et al. report that vasodilators is useful for the treatment of erectile dysfunction. (column 2, lines 6-10).

Drug Facts and Comparisons teaches tamoxifen is commercially available orally. (page 3162, bottom table under Nolvadex).

It would have been obvious to one of ordinary skill in the art to incorporate the agents (i.e. vasodilators) with tamoxifen because vasodilators are useful for the treatment of erectile dysfunction as Zhang et al. One would have been motivated to combine vasodilators with tamoxifen for the treatment of erectile dysfunction in order to achieve at least an additive effect for the treatment of erectile dysfunction. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Moreover, the route of administration of tamoxifen is obvious since oral formulation of tamoxifen is commercially available as taught by Drug Facts and Comparisons.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
August 14, 2006